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10/562,471	11/13/2006	John Graeme Houston	9931-009US	6298
22897 DEMONT & 1	7590 05/23/200 BREYER, LLC	EXAMINER		
100 COMMONS WAY, Ste. 250			TANNER, JOCELIN C	
HOLMDEL, NJ 07733			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/562,471 HOUSTON ET AL Office Action Summary Examiner Art Unit JOCELIN C. TANNER 4133 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 13 November 2006. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-6 and 29-50 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-6 and 29-50 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on 22 December 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

Paper No(s)/Mail Date 12/22/2005

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

This is in response to the application filed on November 13, 2006 in which claims 1-6 and 29-50 are presented for examination.

#### Status of Claims

Claims 1-6 and 29-50 are pending, of which claim 1 is in independent form.

Claims 1-6 and 29-50 are rejected under 35 U.S.C. 102(b).

#### Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/22/2005 was filed before the mailing date of the application on 11/13/2006. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

## Drawings

1. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the dimensional qualities of the internal formations and accurately display the first and second surfaces as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the

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immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 39, 40 and 42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 21, 29 and 30 of copending Application No. 10/300,298 in view of Houston et al (EP 1254645). This is a provisional obviousness-type double patenting rejection.

Detailed mapping of the claims of the instant application to the claims of the copending application are provided in the table below with the differences in bold.

Claims of Instant Application	Claims of Copending Application 10/300298
1. An internal formation for a conduit, the formation comprising a longitudinally extending member adapted to extend along an inside surface of at least a portion of the length of the conduit, the longitudinally extending member having an asymmetric profile in a direction transverse of the longitudinal axis of the member.  39. A conduit comprising an internal formation in accordance with claim 1.	21. A tube for a human or animal body, the tube comprising a flexible tubular material, a side wall of the tube being deformed to form a helical formation in an internal surface of the side wall of the tube, and a corresponding helical indentation in an external surface of the side wall, there being a coating applied to the indentation, the coating ensuring that the helical formation maintains its shape.
40. A conduit according to claim 39, wherein the conduit is blood flow tubing.	29. A tube according to claim 21, wherein the tube is blood flow tubing.
42. A conduit according to claim 41, wherein the vascular prosthesis is a graft.	30. A tube according to claim 21, wherein the blood flow tubing is a graft.

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Claims 21, 29 and 30 of the copending application disclose all of the limitations of the claimed invention except for an asymmetric profile of the longitudinally extending member.

Houston et al teach an internal helical ridging having an asymmetric profile, for e.g., elliptical, for reducing turbulence.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected an asymmetric profile for the internal formation, as taught by Houston et al., with the reasonable expectation that at least one would be successful in reducing turbulence since a person of ordinary skill has good reason to pursue known options within his or her technical grasp.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an elliptical cross-section of Houston (EP 1254645) to the internal formation of Houston (10/300298) for reduction of turbulence.

4. Claims 1, 39 and 40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5, 6 and 21 of U.S. Patent No. 6,776,194 in view of Houston et al (EP 1254645).

Detailed mapping of the claims of the instant application to the claims of the copending application are provided in the table below with the differences in bold.

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Claims of Instant Application	Claims of US Patent No. 6,776,194
An internal formation for a conduit, the formation comprising a longitudinally extending member adapted to extend along an inside surface of at least a portion of the length of the conduit, the longitudinally extending member having an asymmetric profile in a direction transverse of the longitudinal axis of the member.	5.Apparatus for generating rotational flow of a fluid in a conduit, the apparatus comprising a conduit and a structure for the conduit, the structure being placed externally around the conduit in use, and the structure comprising conduit deforming means deforming the side walls of the conduit such that, the deformation of the side walls forms a helical formation within the conduit that generates rotational flow in a fluid flowing through the conduit.
39. A conduit comprising an internal	and the same serving and agreement agreement agreement agreement agreement agreement agreement agreement and agreement agree
formation in accordance with claim 1.	Apparatus according to claim 5, wherein the conduit deforming means comprises internal ridges which define a specific profile of the deformation of the internal side walls.
A conduit according to claim 39, wherein the conduit is blood flow tubing.	21. Apparatus according to claim 20, wherein the conduit comprises artificial or natural blood flow tubing.

Claims 5, 6 and 21 of the copending application disclose all of the limitations of the claimed invention except for an asymmetric profile of the longitudinally extending member.

Houston et al teach an internal helical ridging having an asymmetric profile, for e.g., elliptical, for reducing turbulence.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected an asymmetric profile for the internal formation, as taught by Houston et al., with the reasonable expectation that at least one would be successful in reducing turbulence since a person of ordinary skill has good reason to pursue known options within his or her technical grasp.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an elliptical cross-section of Houston (EP 1254645) to the internal formation of Houston (10/300298) for reduction of turbulence.

### Claim Objections

- Claim 35 is objected to because of the following informalities: The claim is a sentence fragment. Appropriate correction is required.
- Claim 47 is objected to because of the following informalities: Claim 47 is dependent on cancelled claims. Appropriate correction is required.

# Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claims 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 31 recites the limitation "the profile" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim. The claim language is so ambiguous that the structure or structural relationship being claimed is unclear. It is also unclear how a surface "subtends a diameter." It is the Examiner's position that an arc or curved segment is defined by an angle.

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 Regarding claim 47, it is unclear what structure is being claimed since claim 47 depends on cancelled claims.

10. Regarding claim 50, the numerous combinations and formations having different heights, angles and surface combinations, renders the claim vague and indefinite.

### Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 29-37, 39-48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Houston et al (EP 1254645).

Regarding independent claim 1, Houston et al or "Houston" herein, discloses an internal formation for a conduit, the formation having a helical-flow inducing means or a "longitudinally extending member" (FIG. 1, element #12) adapted to extend along an inside surface of at least a portion of the length of the conduit, the longitudinally extending member having an asymmetric profile in a direction transverse of the longitudinal axis of the member (column 2, lines 10-12, 15-10, FIG 1).

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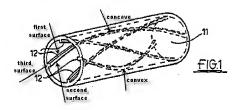
12. Regarding claim 2, Houston discloses a helical-flow inducing means or "longitudinally extending member" (FIG. 1, element #12) that extends helically along the length of the conduit (column 2, lines 1-2 and 7-9, FIG. 1).

- 13. Regarding claim 3, Houston discloses a helical-flow inducing means or "longitudinally extending member" (FIG. 1, element #12) extending helically along the internal side wall of the conduit.
- 14. Regarding claim 4, Houston discloses a first surface of the longitudinally extending member (FIG. 1, element #12) that is at least partially directed towards an inlet of the conduit and a second surface of the longitudinally extending member is at least partially directed towards the outlet of the conduit.
- 15. Regarding claim 5, Houston discloses a first surface of the longitudinal member to have a planar portion and/or a curved portion (FIG. 1). Please see marked up figure below.
- Regarding claim 6, Houston discloses a second surface having a planar portion and/or a curved portion (FIG. 1). Please see marked up figure below.

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- 17. Regarding claim 29, Houston discloses a second surface having a curved portion, the curved portion being concave or convex, or a combination of concave and convex (FIG. 1). Please see marked up figure below.
- 18. Regarding claim 30, Houston discloses a first surface having a curved portion, the curved portion being concave or convex, or a combination of concave and convex (FIG. 1). Please see marked up figure below.



- Regarding claim 31, as best understood, in light of the rejection under 35 U.S.C.
   second paragraph, Houston shows the longitudinal member to be twisted wherein angles are formed with respect to the surface of the conduit (column 6. lines 14-15).
- Regarding claim 32, Houston discloses an angle that the first surface subtends with the diameter of the conduit to be 16°, i.e., less than 20° (column 6, lines 28-30).

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Houston anticipates the claimed range of less than 20° because he discloses a specific value of 16°. A specific value in the prior art which is within a claimed range anticipates

the range. MPEP 2131.03.

21. Regarding claim 33, Houston discloses an angle that the first surface subtends

with the diameter of the conduit as being to be 16°, i.e., between 5° and 50° (column 6,

lines 28-31). Houston anticipates the claimed range of between 5° and 15° because he

discloses a range of between 5° and 50° which encompasses the claimed range. A

specific value in the prior art which is within a claimed range anticipates the range.

MPEP 2131.03.

22. Regarding claim 36, Houston discloses first and second surfaces that extend

from the internal surface of the conduit towards each other and towards a central

longitudinal axis of the conduit (FIG.1). Please see marked up figure above.

23. Regarding claim 37, Houston discloses first and second surfaces that are

coupled together at an apex or by a third surface (FIG.1). Please see marked up figure

above.

24. Regarding claim 38, Houston discloses an internal formation having an apex or a

third surface that is curved (FIG.1). Please see marked up figure above.

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25. Regarding claim 39, Houston discloses an internal formation having a longitudinally extending member with asymmetric profile and extends along an inside surface of a conduit (FIG.1). Please see marked up figure above.

- 26. Regarding claim 40, Houston discloses a blood-flow tubing or "conduit" used for implantation or in devices for improving circulation (column 7, lines 20-22, FIG. 1, element #11).
- Regarding claim 41, Houston discloses a blood flow tubing that is a vascular prosthesis (column 3, lines 12-14).
- Regarding claim 42, Houston discloses a vascular prosthesis that is a graft (column 3, line 39-41).
- Regarding claim 43, Houston discloses a vascular prosthesis that is a stent (column 3. lines 42-46).
- Regarding claim 44, Houston discloses a vascular prosthesis that is a graff/stent combination (column 3. line 39-41).
- Regarding claim 45, Houston discloses a formation that effects spiral flow of a fluid flowing through the conduit (column 1, lines 56-58).

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- Regarding claim 46, Houston discloses a fluid as being a liquid (column 4, lines 27-29).
- 33. Regarding claim 47, Houston discloses a conduit having two or more internal formations (FIG. 1).
- 34. Regarding claim 48, Houston discloses formations that are in parallel around the conduit (FIG. 4) wherein the formations extend in the same direction and do not intersect.
- 35. Regarding claim 50, Houston discloses formations that differ in height and/or the angle of the first and/or second faces by selecting ridges having various shapes or sizes (column 2, lines 3-5).
- 36. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

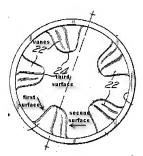
Claims 1, 2, 3, 4, 36, 37, 38, 39, 45, 46, 47, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Jansen (US Patent No. 5,992,465).

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Regarding independent claim 1, Jansen discloses an internal formation for a conduit, the formation having vanes or a "longitudinally extending member" (FIG. 2, element #22) adapted to extend along an inside surface of at least a portion of the length of the conduit, the longitudinally extending member having an asymmetric profile in a direction transverse of the longitudinal axis of the member (column 2, lines 12-18, FIG 2).

- 37. Regarding claim 2, Jansen discloses vanes or a "longitudinally extending member" (FIG. 2, element #22) that extends helically along the length of the conduit (column 3, lines 16-19).
- 38. Regarding claim 3, Jansen discloses vanes or a "longitudinally extending member" (FIG. 2, element #22) extending helically along the internal side wall of the conduit (column 2, lines 12-18).
- 39. Regarding claim 4, Jansen discloses a first surface of the longitudinally extending member (FIG. 1, element #12) that is at least partially directed towards an inlet of the conduit and a second surface of the longitudinally extending member is at least partially directed towards the outlet of the conduit. Please see figure below.

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- 40. Regarding claim 36, Jansen discloses first and second surfaces that extend from the internal surface of the conduit towards each other and towards a central longitudinal axis of the conduit (FIG.2). Please see marked up figure above.
- 41. Regarding claim 37, Jansen discloses first and second surfaces that are coupled together at an apex or by a third surface (column 3, lines 13-14, FIG.2). Please see marked up figure above.
- Regarding claim 38, Jansen discloses an internal formation having an apex or a third surface that is curved (FIG.2).
- 43. Regarding claim 39, Jansen discloses an internal formation having a longitudinally extending member with asymmetric profile and extends along an inside surface of a conduit (column 3. lines 16-20, FIG.2). Please see marked up figure above.

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44. Regarding claim 45, Jansen discloses a formation that effects spiral flow of a fluid flowing through the conduit to decrease turbulence (column 1, lines 60-64).

- 45. Regarding claim 46, Jansen discloses a fluid as being a liquid (column 2, lines 42-45).
- Regarding claim 47, Jansen discloses a conduit having two or more vanes or "internal formations" (FIG. 2, element #22).
- 47. Regarding claim 49, Jansen discloses formations being in series around the circumference of the conduit (FIG. 2, element #22).

## Claim Rejections - 35 USC § 103

- 48. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al (EP 1254645).

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Regarding claim 34, Houston discloses all of the limitations discussed in claim 34 except for an angle that the first surface subtends with the diameter of the conduit being substantially 10°.

Houston teaches an angle in the range of 5° and 50° (column 6, lines 28-31).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected the value of 10° from within the range of 5° and 50°, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over
 Houston et al (EP 1254645) in view of Jansen (US Patent No. 5,992,465).

Regarding claim 49, Houston discloses all of the limitations that were previously discussed in claim 47 except for the internal formations being in series along the conduit.

Jansen teaches vanes that are arranged in succession around the circumference of the conduit to stabilize and maintain flow of different fluids through spacing and varying the number of vanes (column 2, lines 39-42 and FIG. 2, element #22).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a series of vanes, as taught by Jansen, within the conduit, as taught by Houston, to enhance the flow of the traveling fluid and reduce turbulence.

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#### Conclusion

50. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schmitt (US Patent No. 6,099,557), Sawyer (US Patent No. 5,344,425) and Mathur (US Patent No. 6,416,540) are references related to providing support to a vessel and reducing turbulence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/ Examiner, Art Unit 4133 4/21/2008

/Frantz Coby/ Supervisory Patent Examiner Art Unit 4133